US EPA ARCHIVE DOCUMENT

257764
RECORD NUMBER

113201
Shaughnessey Code

2/13/90

REVIEW NUMBER

ECOLOGICAL EFFECTS BRANCH REVIEW

DATE: IN 01-17-90 **OUT** _____

FILE OR REG. NO. 7969-53

PETITION OR EXP NO. _____

DATE OF SUBMISSION _____

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RD ACTION CODE/TYPE OF REVIEW 301 - Amendment Resubmission

TYPE PRODUCT(S): I, D, H, F, N, R, S Fungicide

DATA ACCESSION NO(S). 413251-01

PRODUCT MANAGER NO. Lewis/Stone (21)

PRODUCT NAME(S) Ronilan Fungicide FL (BAS 352 36F)
Vinclozolin

COMPANY NAME BASF

SUBMISSION PURPOSE Review Data

SHAUGHNESSEY CODE	CHEMICAL AND FORMULATION	% A.I.
113201	Ronilan FL (BAS 352 36F)	
	Vinclozolin (499.6 g/l)	50%

MRID: 413251-01

DATA EVALUATION RECORD

1. Chemical: Ronilan FL (BAS 352 36F)

2. Test Material: Ronilan FL (BAS 352 36F) formulated product with Vinclozolin 50% a.i. and 50% inert ingredients

3. Study Type: 96-hour flow-through acute toxicity for freshwater fish. Species tested: rainbow trout *Salmo gairdneri*

4. Study ID: Ronilan FL (BAS 352 36F): Flow-through acute toxicity test to rainbow trout 7964-53; Project No. : 12F0432/885185; Submitted by: BASF AG, Department of Toxicology, Ludwigshafen, West Germany, January 13, 1989; Submitted to: BASF Corporation Chemicals Division

5. Reviewed by: Daniel Balluff, Biologist, EEB/EFED — Signature: Daniel Balluff — Date: 2/13/90

6. Approved by: Henry Craven, Head Section IV, EEB/EFED — Signature: Henry T. Craven — Date: 2/13/90

7. Conclusion:

This study is scientifically sound and fulfills EPA's guidelines for an acute toxicity test for freshwater fish. No mortality occurred in the study. The highest nominal concentration used was 100 mg/l BAS 352 36 F (108.9 mg/l measured concentration). The amount of active ingredient in the formulated product was 50% Vinclozolin. Therefore, the LC_{50} value was determined to be greater than 50 mg/l. The NOEC of BAS 352 36 F is 3.16 mg/l after 96 hours. However, because a control was not used in the test and extensive toxic symptoms were reported at concentration levels 10 mg/l and higher, the results of the study should be viewed with caution.

LC_{50} > 100 mg/L of formulated product (50% ai)

8. Recommendations: N/A

9. Background: N/A

10. Discussion of Individual Tests: N/A

11. Materials and Methods:

a. Test Animals - Rainbow trout Salmo gaindneri; Mean weight: 2.3 g: Mean Length: 6.3 cm; Source: Forellenhof Fredelsloh, Dr. Med. Vet. Otto Mueller D-3413 Moringer 1, FRG. The fish were fed Growing feed F/B 50 ssniff spezialdiaeten gmbh D-4770 Soest, FRG (ad libitum) until one day prior to the exposure.

b. Test System - The flow-through bioassay was conducted in glass aquaria with stainless steel frame containing about 50 liters of reconstituted freshwater. Temperature: 12 ° C; Photoperiod: 16 h light / 8 h dark; Hardness: 2.5 MMOL/L; Dissolved oxygen concentration range: 10.6 - 11.4 mg/l; pH range: 7.5 - 7.8. The test solutions were aerated.

c. Dosing - The following nominal concentrations were tested: 1.00, 3.16, 10.00, and three replicates of 100.00 (mg/l). The corresponding measured concentrations were 0.75, 2.06, 7.31, 99.0, 108.9, and 106.5 (mg/l) respectfully.

d. Design - Four concentrations were tested with 10 rainbow trout per container. Water samples were taken from test solutions at 1, 24, 28, 72, and 96 hours.

e. Statistics - The 96-hour LC_{50} values was not calculated because there was no mortality in the study.

12. Reported Results: The maximum concentration tested causing no mortality was 100 mg/l (BAS 352 36F). The no-observed effect concentration was 3.16 mg/l after 96 hours.

13. Study Authors Conclusion: The 96-hour LC_{50} of Ronilan FL (BAS 352 36F) to rainbow trout was greater than the highest treatment concentration used in the test (100 mg/l).

14. Reviewers Discussion and Interpretation of the Study:

a. Test Procedures - The following discrepancies were noted in the study:

- No control was used in the study.

- The highest test concentration used was 100 mg/l of the formulated product Ronilan FL (BAS 352 36F). The amount of active ingredient of Vinclozolin in the formulation was 50%. Therefore, the highest test concentration was 50 mg/l active ingredient. The highest concentration should be 100 mg/l a.i..

- At 10.00 mg/l nominal concentration rainbow trout exhibited toxic symptoms such as apathy, convulsions, gasping, and side position behavior. The mean weight of rainbow trout used in the study was 2.3 g with a mean body length of 6.3 cm. Although this size class of fish falls within the EPA guidelines, younger trout might have exhibited a much higher rate of mortality under the same test conditions.

- The highest measured test concentration of the formulated product (BAS 352 36 F) in the study was over 100 mg/l. At 50% Vinclozolin in the formulation there should be 50 mg/l of Vinclozolin in the 100 mg/l test concentration. Since the solubility of Vinclozolin is 2.6 mg/l, only a small proportion of the Vinclozolin would actually be dissolved in solution. The rest would be suspended in the test vessels (no precipitate was reported). The test solutions were reported to be cloudy from concentrations 10 mg/l upward, increasing with an increase in the concentration. Therefore, the bioavailability of the suspended Vinclozolin in the test solutions may have been less than if the vinclozolin was completely dissolved in solution. Thus, the toxicity of Vinclozolin in the formulation may be less than what technical Vinclozolin (mixed with an acceptable solvent) would be under the same test conditions.

b. Statistical Analysis - No statistical analysis was performed because there was no mortality in the study.

c. Discussion / Results - The 96-hour LC_{50} value for BAS 352 36 F to rainbow trout is greater than 50 mg/l (a.i. Vinclozolin). > 100 mg/L BAS 352 34F BJM

d. Adequacy of Study

1) Classification: Core

2) Rationale: The discrepancies listed above do not invalidate the study because the test concentrations were measured and no mortality occurred.

3) Repairability: N/A

15. Completion of One-Liner: N/A

RESULTS :

NOMINAL CONC. (MG/L)	NUMBER OF FISH	DEAD FISH AFTER * 1 H	4 H	24 H	48 H	72 H	96 H
1.00	10	0	0	0	0	0	0
3.16	10	0	0	0	0	0	0
10.00	10	0	0	0	0	0	0
100.00	10	0	0	0	0	0	0
100.00	10	0	0	0	0	0	0
100.00	10	0	0	0	0	0	0
0.00	10	0	0	0	0	0	0

NOMINAL CONC. (MG/L)	SYMPTOMS * 1 H	4 H	24 H	48 H	72 H	96 H
1.00						
3.16						
10.00			AT	AKL	AS	AST
100.00			AT	AST	AS	AST
100.00	L	L	AT	AST	AS	AST
100.00	L		AT	AST	AS	AST
0.00						

EXPLANATION OF SYMPTOMS:

A=APATHY
B=ABDOMINAL DISTENSION
E=EXOPHTHALMOS
F=ESCAPE REFLEX
H=HYPERREFLEXIA
K=CONVULSIONS
L=GASPING
N=NARCOTIC-LIKE STATE
T=TUMBLING
U=RESTLESSNESS
V=DISCOLORATION
W=HEADSTAND
X=ACCELERATED RESPIRATION
S=SIDE POSITION

* = FOR CHECKING FOR DEAD FISH AND FOR POSSIBLE SYMPTOMS IN THE CONCENTRATIONS 100 MG/L THE FISH WERE DIRECTED TOWARDS THE FRONT PANE OF THE AQUARIA USING A NET.